REMARKS

Claims 16-18 remain pending for prosecution in this application.

The Rejections under 35 U.S.C. § 102

Claims 16-17 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Xu et al. Moreover, Claims 16-17 stand rejected under 35 U.S.C. §§ 102(a) and 102(e) as allegedly being anticipated by Gish et al. Applicants respectfully traverse the rejections.

Applicants first note that it is a long accepted premise of patent law that in order for a publication to anticipate a claimed invention, it must teach "each and every element" of the invention "as it is claimed". For example, Applicants respectfully direct the Examiner to Hybritech, Inc. v. Monoclonal Antibodies, Inc. 2231 USPQ 81, 90 (Fed. Cir. 1986) where the Federal Circuit stated:

> "anticipation [under 35 U.S.C. § 102] requires that disclosure in a prior art reference of each and every element as set forth in the claim". (Emphasis added).

As such, the Federal Circuit has made clear that a rejection under 35 U.S.C. § 102 is proper only when the cited reference teaches every element of the claimed invention as those elements are explicitly recited in the claims. For the purpose of a method claim (such as that set forth in the present patent application), this clearly means that the cited reference must each and every method step as it appears in the rejected claim.

Current independent Claim 16 is directed to a method of diagnosing the presence of a prostate tumor in a mammal. A necessary step of the claimed method as explicitly recited in independent Claim 16 is "determining the level of expression of a gene encoding the polypeptide shown as SEQ ID NO:123".

Do either the Xu et al. or Gish et al. references cited by the Examiner in the present Office Action teach this method step? Of course, they do not. Neither the Xu et al. nor the Gish et al. reference disclose a polypeptide having the same amino acid sequence as that disclosed in the present application as SEQ ID NO:123 and, as such, neither do they teach the step of measuring the expression of a gene that encodes a polypeptide having that amino acid sequence. Therefore, neither

of these references explicitly teaches the required method step of the present claim, i.e., measuring the expression of a gene encoding the polypeptide of SEQ ID NO:123. Under established case law, therefore, neither of these references can support a rejection under 35 U.S.C. § 102.

The Examiner's reasoning hinges on the fact that while both Xu et al. and Gish et al. fail to teach the actual polypeptide disclosed in the present specification as SEQ ID NO:123, they both teach polypeptides having stretches of sequence identity to that of SEQ ID NO:123. Given this, the Examiner argues that certain oligonucleotide probes as taught by the cited references could be used to measure the expression of the gene encoding SEQ ID NO:123, thereby supporting an anticipation rejection.

Applicants agree with the Examiner's statements about the Xu et al. and Gish et al. discloses. It is true that both references teach polypeptides that are similar, but not identical, to that of SEQ ID NO:123. It is also true that one could design oligonucleotide probes that would be expected to be useful for measuring the expression of both the Xu et al./Gish et al. genes as well as the gene encoding the polypeptide of current SEQ ID NO:123. But these arguments are certainly irrelevant as to the central question...whether the Xu et al. and Gish et al. references teach the step of "measuring the expression of a gene encoding the polypeptide of SEQ ID NO:123". As stated above, since neither of the cited references teach nor render obvious the polypeptide of SEQ ID NO:123, neither of these references can possibly anticipate a method claim that explicitly requires the step of measuring the expression of a gene that encodes the polypeptide of SEQ ID NO:123.

In light of the above, Applicants believe that the outstanding rejections under 35 U.S.C. § 102 are improper and should, therefore, be withdrawn. Applicants believe that this application is now in condition for immediate allowance and respectfully request that the outstanding rejections be withdrawn and this case passed to issue.

The Examiner is invited to contact the undersigned at (650) 225-4461 if any issues may be resolved in that manner.

Respectfully submitted,

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